

4-26-04



Express Mail No. EV 335 859 637 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Zeligs Confirmation No.:

Serial No.: 10/765,792 Art Unit:

Filed: January 26, 2004 Examiner: To be assigned

For: PHYTOCHEMICALS FOR Attorney Docket No.: 9439-016
TREATMENT OF MASTALGIA
AND ENDOMETRIOSIS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of :

☒ Each U.S. patent application publication and U.S. and foreign patent;

☒ Each publication or that portion which caused it to be listed on the PTO-1449;

☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;

☐ all other information or portion which caused it to be listed on the PTO-1449.

1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.

1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.

2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):

☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);

☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

- ☒ Before the mailing of the first Office action on the merits;
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
- ☐ to be charged to Jones Day Deposit Account No. 503013.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The Certification Statement in Item 5 below is applicable.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Jones Day Deposit Account No. 503013.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
6. ☒ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. , filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:

(Check Item 8a, 8b, or 8c)

- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 503013.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: April 23, 2004

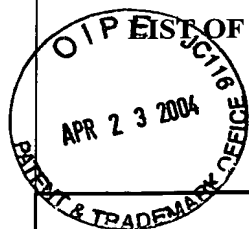
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LIST OF REFERENCES CITED BY REQUESTOR

(Use several sheets if necessary)

ATTY DOCKET NO.

9439-016

APPLICATION NO:

10/765,792

APPLICANT

Michael A. Zeligs

FILING DATE:

Jan 26, 2004

GROUP

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	6,613,792	09/02/2003	Ellenberger et al.			
	A02	6,399,645	07/04/2002	Bell et al.			
	A03	6,086,915	07/11/2000	Zeligs			
	A04	5,948,808	09/07/1999	Safe			
	A05	5,830,887	11/03/1998	Kelly			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

C01	Arbeit, JM <i>et al.</i> , "Chronic estrogen-induced cervical and vaginal squamous carcinogenesis in human papillomavirus type 16 transgenic mice", 1996 Apr., Proc Natl Acad Sci, USA 93:2930-2935.
C02	Baugh SM <i>et al.</i> , "Treatment of cervical dysplasia with indole-3-carbinol" in The Ray A. Barlow Scientific Symposium, 1998 Jan 23, Shreveport : The Center for Excellence in Cancer Research, Treatment and Education, Louisiana State University Medical Center, Shreveport (LA), pg. 3.
C03	Bell, MC <i>et al.</i> , "Placebo-controlled Trial of Indole-3-Carbinol in the Treatment of Cervical Dysplasia", 1999 March, Gynecol. Oncol. 72:446
C04	Bell, MC <i>et al.</i> , "Placebo-Controlled Trial of Indole-3-Carbinol in the Treatment of CIN", 2000, Gynecologic Oncology, 78:123-129.
C05	BioResponse-DIM Indolplex Product Information Brochure, 1998 Dec 15.
C06	Bradfield et al., "High-performance liquid chromatographic analysis of anticarcinogenic indoles in Brassica oleracea", 1987, J Agric Food Chem 35:46-49
C07	Bradlow et al., "2-hydroxyestrone: the 'good' estrogen", 1996, J Endocrin 150:S259-S265
C08	Cancer Medicine 3rd edition, 1993, JF Holland ed., Lea & Febiger, Malvern, PA p. 1633.
C09	Chen et al., "Aryl hydrocarbon receptor-mediated antiestrogenic and antitumorigenic activity of diindolylmethane", 1998, Carcinogenesis 19:1631-1639
C10	December 1998 Bioresponse Letter, 1998 Dec 29.
C11	Greenblatt et al., "Clinical studies with an anti-gonadotropin -danazol", 1971, Fertil Steril 22:102.
C12	Ho et al., "Urinary 2/16alpha-hydroestrone ratio: correlation with serum insulin-like growth factor binding protein-3 and a potential biomarker of breast cancer risk", 1998, Ann Acad Med Singapore 27:294-9
C13	Jin et al., "Indole-3-carbinol prevents cervical cancer in human papillomavirus type 16 (HPV16) transgenic mice", 1999, Cancer Res 59:3991-7
C14	Komura et al., "Catecholestrone as a natural antioxidant", 1996, Ann NY Acad Sci 786:419-29

C15	Michnovicz et al., "Changes in levels of urinary estrogen metabolites after oral indole-3-carbinol treatment in humans", 1997, J Natl Cancer Inst 89:718-23
C16	Molecular Biology of the Cell 2 nd ed., 1989, Alberts, B et al., Garland Publishing, Inc., New York, pp. 1193-1194, 1204-1206.
C17	Ponten J and Guo Z, "Precancer of the Human Cervix", 1998, Cancer Surveys 32:201-229.
C18	Rosen et al., "Preliminary results of the use of indole-3-carbinol for recurrent respiratory papillomatosis", 1998, Otolaryngol Head Neck Surg 118:810-5
C19	Schneider et al., "Abnormal oxidative metabolism of estradiol in women with breast cancer", 1982, Proc Natl Acad Sci USA 79:3047-52
C20	Telimaa et al., "Placebo-controlled comparison of danazol and high-dose medroxyprogesterone acetate in the treatment of endometriosis", 1987, Gynecol Endocrinol 1:51
C21	Thomas et al., "Impact of gestrinone on the course of asymptomatic endometriosis", 1987, Br Med J 294:272.
C22	Tzingounis et al., "Modern approach to endometriosis", 1997, Annals New York Acad Sci 816:320-330.
C23	Yuan F <i>et al.</i> , "Prevention of Papillomavirus initiated cancer by the phytochemical Indole-3-Carbinol", Proceedings of the 17 th International Papillomavirus Conference, 1999 Jan 9-15, pg. 73.
C24	Zeligs MA, "Diet and Estrogen Status: The Cruciferous Connection", 1998, J Med Food, 1:67-82.

EXAMINER	DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	